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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,178	09/30/2003	Marco Pinna	243129US0	1258

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EXAMINER	
FERNANDEZ, SUSAN EMILY	
ART UNIT	PAPER NUMBER
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	02/26/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/26/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/673,178	PINNA ET AL.	
	Examiner	Art Unit	
	Susan E. Fernandez	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8 and 9* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment and terminal disclaimer filed December 11, 2006, have been received and entered.

Claims 1-9 are pending. Claim 7 is withdrawn. Claims 8 and 9 are new.

Claims 1-6 and 8-9 are examined on the merits.

Claim Objections

Claim 1 is objected to because of the following informalities: The recitation "a total weight of the film" at lines 4 and 5 should be replaced with "the total weight of the film." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 8-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, claim 1 now recites that "the at least one starch and the at least one cellulose compound are selected so as to be capable of binding to one another in stable form," which

constitutes new matter. Page 5, lines 4-5 is the only instance in the disclosure which speaks of the binding of the starch and cellulose in stable form. However, this section of the disclosure does not indicate that the selection of the starch and the cellulose compound is so that they are capable of binding to one another in stable form. Because the specification as filed fails to provide clear support for the new claim language, a new matter rejection is clearly proper.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "low" and "high" in claim 1 are relative terms which render the claim indefinite. The recitations "low molecular weight" and "high amylopectin content" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thus, claims 1-6 and 8-9 are rejected under 35 U.S.C. 112, second paragraph.

Claim 1 is also rendered indefinite by the recitation "the at least one starch and the at least one cellulose compound are selected so as to be capable of binding to one another in stable form." This recitation does not require that the at least one starch and the at least one cellulose must bind to one another in stable form in the claimed film, thus it is not clear how the recitation further limits the invention. Thus, claim 1-6 and 8-9 are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Xu et al. (US 6,419,903).

Xu et al. discloses a "rapidly dissolvable orally consumable film composition" comprising "water soluble, low viscosity hydroxyalkylmethyl cellulose and water dispersible starch and a flavoring agent" (abstract).

Xu et al. teaches that the cellulose is present in the film composition in an amount ranging from about 10 to about 60% by weight (column 3, lines 8-11), which meets the cellulose weight requirements recited in instant claim 1. Further still, Xu et al. teaches that the hydroxyalkylmethyl cellulose may be hydroxypropyl methyl cellulose (claim 2), thus meeting limitations in instant claims 1 and 4.

The pregelatinized starch in the film composition is present in an amount ranging from about 5 to about 50% by weight (column 3, lines 47-49), which fits within the weight range recited in instant claim 1.

The flavoring agent can be considered a cosmetic, aromatic, pharmaceutical and/or food substance. Moreover, this flavoring agent is present in the film composition in an amount ranging "from about 2.0 to about 10% by weight" (column 4, lines 3-6). Given that "about 10%"

embodies percentages above 10%, such as 10.1%, the Xu invention clearly anticipates instant claim 1 which requires an active substance in an amount of from 10 to 50% by weight relative to the total weight of the film composition. Moreover, the composition can further comprise active breath freshening agents (column 4, line 40-42) which may be present in the composition at a concentration of about 0.1 to about 2.0% by weight (column 4, lines 46-49). These breath freshening agents can be considered additional active substances, thus contributing to the amount of active substances present in the film composition. Even if the flavoring agent were present in amount of 10% by weight of the composition, the presence of the breath freshening agents result in a composition comprising active substances in a concentration of more than 10% by weight of the composition.

Xu et al. also teaches that the film composition quickly dissolves in the mouth and "...generally in less than 30-40 seconds" (column 2, lines 57-58). Thus, the film composition can dissolve at lengths of time shorter than 30-40 seconds, including 10 seconds and 7 seconds. Moreover, lengths of time shorter than 30-40 seconds can be considered a dissolution time of "a few seconds." Thus, the Xu invention meets the dissolving time limitations recited in instant claims 1, 8, and 9.

Finally, in the preparation of the Xu invention, the starch forms a homogeneous mixture with cellulose (column 4, lines 54-63). Thus, the starch binds to the cellulose in a stable form.

A holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. in view of Hata (US 4,345,032) and Sharik (US 5,206,026).

As discussed above, Xu et al. anticipates claims 1, 4, 8, and 9. However, Xu et al. does not expressly disclose that bacteria is present in the disclosed composition.

Hata discloses that specific lactobacillus strains have the ability to deodorize foul breath (column 1, lines 42-45).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have substituted the flavoring agent of the Xu invention with specific lactobacillus strains appropriate for deodorizing foul breath. One of ordinary skill in the art

would have been motivated to do this since these lactobacillus strains would have served as breath freshening agents, as required by the Xu invention.

Xu et al. also differs from the instant invention in that it does not teach a composition comprising hydroxyethyl cellulose or hydroxypropyl cellulose.

Sharik discloses an instantaneous delivery film for the delivery of a therapeutic agent (abstract), wherein the delivery film comprises of a film-forming polymer which must be water soluble (column 3, lines 15-27). Suitable film-forming polymers include hydroxyethyl cellulose and hydroxypropyl cellulose.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have modified the Xu invention such that hydroxyethyl cellulose or hydroxypropyl cellulose is used as the cellulose of the Xu invention. One of ordinary skill in the art would have been motivated to do this since these celluloses would have enabled the formation of a film. Thus, a holding of obviousness is clearly required.

Response to Arguments

The terminal disclaimer filed on December 11, 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application Number 10/680,115 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Applicant's arguments filed December 11, 2006, with respect to the rejection of claims 1-6 over Xu et al., Hata, and Sharik, have been fully considered but they are not persuasive. Applicant asserts that Xu et al. does not teach the claimed invention as it teaches a pre-

gelatinized starch rather than a starch of low molecular weight and high amylopectin content. However, it is respectfully noted that the instant claims do not recite that the starch cannot be pre-gelatinized. Furthermore, neither the instant claims nor the instant specification indicate what molecular weights are considered low, or what amylopectin contents are considered high. Thus, a starch of any molecular weight and amylopectin content meet the limitations of the claims. Moreover, given that the starch of the Xu invention can be a starch of maize (column 3, lines 32-36) which is one of the starches appropriate for the instant invention (page 4, lines 15-16), the starch of Xu et al. meets the molecular weight and amylopectin content requirements recited in the claims.

With respect to the dissolution time of the Xu invention, it is noted that Xu et al. states that the dissolution time is "...generally **in less** than 30-40 seconds" (column 2, line 58, emphasis added) and thus the Xu invention permits dissolution times such as 7 and 10 seconds. Moreover, even if Xu et al. were silent as to the exact dissolution time, section II of M.P.E.P 2112.01 points out the following:

"'Products of identical chemical composition can not have mutually exclusive properties.' A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present."

Additionally, applicant asserts that the active ingredient (flavoring) of Xu et al. is from about 2.0 to 10% by weight, and thus does not meet the instant claim limitations. However, it is respectfully noted that the instant claims require that the active substance is present in "...an amount of from 10 to 50% by weight..." which means that the lower limit is 10%. As pointed

out above, Xu et al. teaches that the active ingredient (flavoring) is in an amount "...ranging from about 2.0 to about 10% by weight" (column 4, lines 3-5), which comprises 10%, thus meeting instant claim limitations. Further still, the disclosed range also comprises percentages above 10% as "about 10%" comprises percentages above 10%. Moreover, active breath freshening agents may also be present and be considered active substances in the Xu invention.

In sum, Xu et al. indeed includes the components of the film of claim 1 in the recited amounts, where the components have the recited properties and result in a film with the recited dissolution time. Thus, the rejections must be maintained over Xu et al., Hata, and Sharik.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

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